K033150 1/1

510(k) Summary

MAR - 1 2004

Date
September 29, 2003

Submitter
Advanced Medical Technologies AG
Kasteler Strasse 11
66620 Nonnweiler-Braunshausen
Germany

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Posterior spinal system

Classification name
Spondylolisthesis spinal fixation device system 888.3070
Pedicle screw spinal system 888.3070
Spinal interlaminal fixation orthosis 888.3050

Equivalent Device
The ART Posterior Spinal System is similar in design, material and indications as the ISOBAR Pedicle Screw System (Scient'x, K990118 and K013444).

Device Description
Pedicle Screws, monoaxial and polyaxial, are available in various lengths and diameters. The Screw is connected to the Rod via a Rod Connector. Rods are Ø6mm in lengths ranging from 40mm to 500mm. The Screw is inserted through an opening in the Connector and inserted in the bone. As a top loading system the Connector has a U-shaped opening that accepts the Rod. The interior of the U-shaped opening in the Connector is threaded to accept a Locking Nut that securely fixes the Rod to the Connector. The necessity for rod bending is reduced by the ability to vary the angle between the screw and connector up to 20°.

A rod connector component, called a Domino, attaches two rods for use in multi-level fusions. Rods can be connected in series or parallel.

A Cross Connector, of varying lengths, attaches to the rods to provide rotational stability to the construct.

Pedicle, laminar and transverse hooks are also part of the system. The rods attach to the hooks and can be used for single or multiple level fixations.

Intended Use
The ART Posterior Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system ART Posterior Spinal System is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The hooks are intended for posterior, nonpedicle screw fixation of the noncervical spine; hook and sacral/iliac screw fixation to the noncervical spine; and hook and sacral screw fixation to the T1-S1 spine.

Summary Nonclinical Tests
Testing was performed according to ASTM F1717.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Advanced Medical Technologies AG
C/o Mr. J.D.Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K033150
Trade/Device Name: ART Posterior Spinal System
Regulatory Number: 21 CFR 888.3070, 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: February 14, 2004
Received: February 23, 2004

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K033150

Device Name: **ART Posterior Spinal System**

Indications for Use:

K033150

ART Posterior Spinal System
Indications for Use

The ART Posterior Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

(Optional format 1-2-96) _____

(Division Sign-off)
Division of General, Neurological
and Restorative Devices

Miriam C. Provost

(Division Sign-Off) 510(k) Number_____
Division of General, Restorative and Neurological Devices

510(k) Number K033150